REMARKS

In the Office Action, claims 1, 15, and 20 are provisionally rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1, 9, and 16 of copending Application No. 10/657,897.

In the Office Action, claims 15 and 20 are provisionally rejected on the ground of nonstatutory obviousness type double patenting as being unpatentable over claims 1, 9, and 16 of copending Application No. 10/657,840.

In the Office Action, claim 8 is rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential steps.

In the Office Action, claim 18 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

In the Office Action, claims 1, 2, 4, 5, 7-12, 15, 16, and 18-21 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application No. 2003/0208241 to Bradley et al.

In the Office Action, claims 3 and 17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bradley et al.

In the Office Action, claim 13 is rejected under 35 U.S.C. §103(a) as being unpatentable over Bradley et al. in view of U.S. Patent No. 6,058,328 to Levine et al.

In the Office Action, claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In response thereto, claims 8 and 18 have been amended. Accordingly, claims 1-21 are now pending. Following is a discussion of the patentability of each of the pending claims.

Preliminary Matter

In the Office Action, claims 1, 15, and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, and 16 of copending Application Serial No. 10/657,897. In response thereto, a terminal disclaimer in compliance with 37 CFR Section 1.321(c) and signed by the undersigned attorney is enclosed herewith that obviates the above provisional double patenting rejection.

In the Office Action, claims 15 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, and 16 of copending Application Serial No. 10/657,840. In response thereto, a terminal disclaimer in compliance with 37 CFR Section 1.321(c) and signed by the undersigned attorney is enclosed herewith that obviates the above double patenting rejection.

In response to the rejection of claims 8 and 18 under 35 U.S.C. §112, second paragraph, the following amendments have been made: claim 8, line 1, "if" has been replaced with --the--; claim 8, lines 2-3, "has been selectively enabled, then performing the following:" has been replaced with –comprises–; and claim 18, line 3, "the" has been replaced with --an--. Accordingly, it is respectfully requested that the rejection of claims 8 and 18 be withdrawn.

Independent Claim 1

Claim 1 recites a method comprising detecting loss of capture of pacing pulses during preventive overdrive pacing using a capture detection unit, detecting tachycardia occurring subsequent to a loss of capture using the tachycardia detection unit, determining, for each tachycardia occurring following a loss of capture, whether the tachycardia spontaneously terminates, and selectively enabling automatic switching from preventive overdrive pacing to ATP therapy based on a percentage of spontaneously terminating episodes of tachycardia occurring subsequent to loss of capture during preventive overdrive pacing.

In accordance with the specification of the present application, antitachycardia pacing (ATP) therapy is most effective if applied early during the tachycardia. Unfortunately, conventional techniques for detecting the onset of a tachycardia do not detect the tachycardia as promptly as would be desired. One technique for detecting an atrial tachycardia is to monitor the atrial rate and initiate ATP if the heart rate exceeds a certain threshold. It may take a fair number of cardiac cycles before the stimulation device can reliably detect a high atrial rate and, in particular, distinguish a high heart rate from a temporary shortening of an atrial heart rate interval caused by a premature beach such as a premature atrial contraction. Another known method is to differentiate pathologic rhythms from normal physiologic rhythms by analyzing heart rate stability. Again, a fair number of cycles may be required before the stimulation device can reliably distinguish a change in heart rate stability caused by a tachycardia from one caused by premature beats or other transient factors. Thus, conventional tachycardia detection techniques do not always detect tachycardia as quickly as desired, resulting in a reduced likelihood that subsequent therapy will be successfully.

The present application provides improved techniques for promptly and reliably detecting tachycardia, wherein tachycardia is detected based on a loss of capture of pacing pulses. For example, so long as each pulse is captured, preventive atrial overdrive pacing is performed continuously. If a pulse fails to capture, the loss of capture may be the result of an onset of an atrial tachycardia. More specifically, a sudden increase in atrial rate due to the tachycardia may have caused the atria to beat before the overdrive pulse could be delivered, rendering atrial tissue refractory at the time the overdrive pulse was delivered. Hence, the overdrive pulse is not captured and a loss of capture is detected. Atrial tachycardia is thereby detected and appropriate steps are taken to respond to the atrial tachycardia.

The Bradley et al. reference is directed to providing capture verification during overdrive pacing. In accordance with the Bradley et al. reference, in an attempt to avoid loss of capture during overdrive pacing, conventional devices typically set the magnitude of the overdrive pulses to be quite high so as to assure that the overdrive pulses are captured. The need to apply overdrive pacing pulses with high pulse

magnitude operates to deplete the power supply of the implantable cardiac stimulation device. The Bradley et al. reference addresses this problem by providing an overdrive pacing technique that permits a reduction in the average magnitude of overdrive pacing pulses while still achieving adequate capture. A control unit control unit controls a pulse generator to overdrive pace the heart at an overdrive pacing rate with each pulse set to a standard pacing pulse magnitude. The control unit performs capture verification on each overdrive pacing pulse. If a pulse fails to evoke capture, the pulse generator is controlled to generate a backup pulse having a pulse magnitude greater than a standard overdrive pulse magnitude for delivery to heart tissue. By providing capture verification of overdrive pacing pulses, the pulse magnitude of each overdrive pulse can be reduced as compared with systems wherein capture verification of overdrive pulses is not performed and wherein, instead, overdrive pulses are merely set to a high pulse magnitude in an attempt to ensure capture.

In accordance with another aspect of the invention of the Bradley et al. reference, standard overdrive pulse magnitude is determined by performing an automatic capture threshold detection search. The threshold detection search may be performed, for example, whenever two consecutive overdrive pulses fail to evoke capture within a single dwell time. When two consecutive loss of captures are detected, the overdrive pulse magnitude is incrementally increased until two consecutive captures are detected. A safety margin is added to the resulting pulse magnitude to yield a new standard overdrive pulse magnitude. A backup pulse is issued after every beat that is not captured during the capture threshold assessment. By providing for automatic capture threshold detection searches, the standard pulse magnitude of the overdrive pulses can be kept as low as possible while still ensuring that substantially all overdrive pulses are properly captured.

The Bradley et al. reference does not disclose or suggest detecting tachycardia occurring following a loss of capture using the tachycardia detection unit. According to the Office Action, paragraph 0003 of the Bradley et al. reference states that a cardiac stimulation device will sometimes induce artificial tachycardia in order to prevent actual tachycardia during overdrive pacing and that this tachycardia will spontaneously

terminate without treatment. It is noted that claim 1 of the present application recites detecting the occurrence of tachycardia subsequent to a loss of capture, whereas the induced artificial tachycardia, as described in the Bradley et al. reference, results from captured overdrive pacing pulses. As such, the Bradley et al. reference discloses detecting induced artificial tachycardia during capture of overdrive pacing pulses. In addition, the induced artificial tachycardia spontaneously terminates as a result of termination of the overdrive pacing pulses, whereas claim 1 is directed to spontaneous termination of tachycardia resulting from an event other than termination of overdrive pacing pulses because loss of capture of the overdrive pacing pulses has previously occurred.

Furthermore, the Bradley et al. reference does not disclose or suggest selectively enabling automatic switching from preventive overdrive pacing to ATP therapy based on a percentage of spontaneously terminating episodes of tachycardia occurring subsequent to loss capture during preventive overdrive pacing. In the Bradley et al. reference, upon loss of capture of pacing pulses, the device continues overdrive pacing and simultaneously performs an automatic capture threshold detection search to determine the proper setting to deliver the overdrive pacing pulses.

Furthermore, it is not inherent for the device described in the Bradley et al. reference to perform the method recited in claim 1 of the present application. In accordance with Section 2112 of the MPEP, the Office Action must provide rationale or evidence tending to show inherency. The fact that a certain result or characteristic may result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 f.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). As there is no rationale or evidence tending to shown

inherency, any rejection of claim 1 would fail to present a prima facia case of anticipation.

The Levine et al. reference is cited in combination with the Bradley et al. reference because it allegedly discloses a device that has a premature atrial contraction (PAC) detection unit. The Levine et al. reference does not disclose or suggest detecting tachycardia occurring following a loss of capture using a tachycardia detection unit. Furthermore, the Levine et al. reference does not disclose or suggest selectively enabling automatic switching from preventive overdrive pacing to ATP therapy based on a percentage of spontaneously terminating episodes of tachycardia occurring subsequent to loss capture during preventive overdrive pacing.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

Dependent Claims 2-14

Claims 2-14 depend from claim 1 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 15

For at least the same reasons discussed previously with regards to claim 1, it is respectfully submitted that claim 15 is in condition for allowance. Furthermore, the Bradley et al. and Levine et al. references do not disclose or suggest a capture-based tachycardia detection unit operative to detect a tachycardia based upon loss of capture of pacing pulses. These references detect tachycardia based on conventional methods such as determining heart rate, morphology template comparison, etc.

Dependent Claims 16-19

Claims 16-19 depend from claim 15 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 20

For at least the same reasons discussed previously with regards to claim 1, it is respectfully submitted that claim 20 is in condition for allowance.

Dependent Claim 21

Claim 21 depends from claim 20 and is similarly patentable. Accordingly, it is respectfully submitted that claim 21 is in condition for allowance.

CONCLUSION

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

6/8/06
Date

Ronald S. Tamura, Reg. No. 43,179
Patent Attorney for Applicant
818-493-3157

Enclosures: (2) Terminal Disclaimers Under 37 CFR 1.321(c)

CUSTOMER NUMBER: 36802